K123269

510(K) SUMMARY

PROcedure™ Rehearsal Studio

JAN 29 2013

510(k) Number K_____

Prepared on:

October 16, 2012

Applicant's Name:

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Contact Person:

Shoshana (Shosh) Friedman
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Trade Name:

PROcedure Rehearsal Studio™

Classification Name:	System, Image Processing, Radiological
Regulation Number:	892.2050
Product Code:	LLZ
Classification:	Class II
Review Panel:	Radiology

Predicate Device:

- PROcedure Rehearsal Studio™ cleared for marketing under K112387

Device Description:

The Simbionix PROcedure Rehearsal Studio software allows clinicians to create a patient specific 3D anatomical model based on a patient's CT for the purpose of

simulating, analyzing and evaluating for preoperative surgical treatment options.

Once the 3D segmentation model has been exported to the Simbionix ANGIO Mentor Simulator Practice Environment, the physician can use it to create a library of modules for training and post-operative debriefing.
The modifications subject to this Special 510(k) submission are: (1) Graphic User Interface changes in various locations; (2) functional change in various locations which include the addition of a TEVAR module that allows the software to create 3D models of chest scans in addition to the EVAR and carotid options that were previously cleared.

Intended Use:

The PROcedure Rehearsal Studio software is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner to an output file. It is also intended as pre-operative software for simulating/evaluating surgical treatment options.

Performance Data:

The company has performed extensive verification and validation activities to ensure the device performs according to its specifications. The verification stage of the software consisted of tests performed for each phase of the user work flow, verifying: Correct functionality of each of the software features, which are part of this work phase and Correct UI. The validation stage consisted of a high level integration test of the device module and included a run through of 10 additional datasets, verifying work flow of all software components. The testing activities were conducted according to the following phases of the user work flow: Importing Patient Data, Segmentation and Centerlines. All testing met the Pass criteria.

Conclusion:

Simbionix Ltd. believes that, based on the information provided in this submission, the modified PROcedure Rehearsal Studio™ is substantially equivalent to the predicate PROcedure Rehearsal Studio previously cleared for marketing under K112387 without raising any new safety and/or effectiveness issue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 29, 2013

Simbionix Ltd
c/o Ms. Shoshana Friedman, RAC
Regulatory Consultant
Push-Med LLC
1914 J.N. Pease Place
CHARLOTTE NC 28262

Re: K123269
Trade/Device Name: PROcedure Rehearsal Studio™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 21, 2012
Received: December 26, 2012

Dear Ms. Friedman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Sean M. Boyd -S for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K123269

Device Name:

PROcedure™ Rehearsal Studio

Indications for Use:

The PROcedure Rehearsal Studio software is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner to an output file. It is also intended as pre-operative software for simulating/evaluating surgical treatment options.

Prescription Use __X__ AND/OR Over-the-Counter Use____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-Vitro Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123269